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Title: Differences in outcomes between type 2 diabetes and non-type 2 diabetes
patients in a local specialist weight management service

Date: 2014

Originally published as: University of Chester MSc dissertation

Example citation: Taylor, I. (2014). *Differences in outcomes between type 2 diabetes
and non-type 2 diabetes patients in a local specialist weight management service.*
(Unpublished master's thesis). University of Chester, United Kingdom.

Version of item: Submitted version

Available at: <http://hdl.handle.net/10034/344412>

University of Chester
MSc Weight Management – Research Project

**Differences in outcomes between type 2 diabetes and non-type 2
diabetes patients in a local specialist weight management service**

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Assessment Number: J03678

Word Count: 8299

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Overweight and obesity in type 2 diabetes.

Abstract

'Diabesity', the comorbid occurrence of type 2 diabetes (T2DM) with obesity, is increasing rapidly in the UK, and becoming more prevalent in younger age groups. The onset of diabetes increases risk of macro- and microvascular complications, reduced life expectancy, and decreased economic productivity and quality of life. It is also expensive to manage, through medication costs, monitoring, and management of complications.

Management of obesity can improve diabetes control, but weight loss is often slower than in those without diabetes. This is often made more challenging over time, with disease progression increasing the number of medications required for glycaemic control.

Dietary methods for weight loss in diabesity have been explored; restricting energy intake and regular support appears to be of more importance to success than macronutrient balance, although long-term effectiveness is unclear. However, bariatric surgery is the only current treatment option offering both the possibility of diabetes remission as well as substantial long-term weight loss.

Specialist diabesity services, supported by a multidisciplinary team to manage outcomes for obesity and diabetes concurrently, have been piloted. However, these services are not commonly available at local level. It is unclear whether the existing obesity management service provision is adequately supporting weight loss for those with comorbid type 2 diabetes.

Introduction

‘Diabesity’ describes the occurrence of type 2 diabetes (T2DM) in obesity. As levels of both obesity and diabetes have risen in the UK in recent decades (Gonzalez, Johansson, Wallander & Rodriguez, 2009) weight loss is acknowledged as an important part of diabetes management (Lau & Teoh, 2013). There is limited high-quality large-scale trials informing formal dietary guidelines for obesity management in T2DM, and dietary composition is considered to be less important than creating an energy deficit (Diabetes UK, 2011). However, studies into the effect of different dietary strategies are ongoing, and in this literature review evidence behind common approaches are summarised.

In addition, what is known about the physiological causes of diabesity is discussed, and the risks of the rise of diabesity to the individual and to health service provision is consolidated. Evidence consistently supports the use of bariatric surgery as a diabetes management – or indeed remission – strategy (Arterburn et al., 2013), but recent pilot schemes designed to tackle both the diabetes and obesity aspects of diabesity holistically have shown promise, and these are also explored.

Diabetes and obesity as a growing concern

Globally, diabetes is increasing in prevalence, exceeding projected estimates previously made (Guariguata et al., 2014). In the UK, prevalence has risen from 2.8% of adults in 1996, to 4.3% of adults in 2005 (Gonzalez, Johansson, Wallander & Rodriguez, 2009). It is currently estimated that nearly 3 million adults (between 20 and 79 years) in the United Kingdom have diabetes (Guariguata et al., 2014). Around 90% of those with diabetes have type 2 (NHS Choices, 2012). In part the rise in the UK over recent decades may be attributed to the

increased ethnic diversity of its population (Abate & Chandalia, 2003), and to the ageing population developing diabetes in later life (Diabetes UK, 2012). However predominantly the rise in diabetes can be contributed to the increase in obesity as the most influential risk factor for T2DM (Diabetes UK, 2012).

Incidence in the UK has also increased in younger age groups, the proportion of diabetes diagnoses occurring across age groups shifted towards younger adults between 1991 and 2000. This is likely to be due to a higher number of younger adults developing T2DM (Holden et al., 2013), but may also reflect improved screening of younger adults and diagnosis at its earlier stages.

The nature of the relative risk between increased body mass index (BMI) and onset of diabetes is debated. Studies have independently suggested that for each additional BMI unit the relative risk of developing T2DM increased linearly by 1.18 (Hartemink, Boshuizen, Nagelkerke, Jacobs, & van Houwelingen, 2006, Schmidt et al., 2013), whereas other studies have suggested a non-linear relationship (Abdullah, Peeters, de Courten & Stoelwinder, 2010). Accepting that multiple confounding modifiable and non-modifiable factors could impact on the risk of an individual developing T2DM, a meta-analysis of international studies concluded that an overweight person (BMI 25 to 30 kg/m²) incurs three times the risk of developing T2DM, and an obese person (BMI >30kg/m²) is seven times more at risk, compared to someone of BMI <25kg/m² (Abdullah, Peeters, de Courten & Stoelwinder, 2010).

The metabolic link between obesity and T2DM is twofold: firstly as a consequence of increased non-esterified fatty acids (NEFAs) in the liver and circulating from the adipose tissue. NEFAs taken up by the pancreas inhibit insulin secretion, and free fatty acids taken up by muscle tissue and in the liver reduce insulin signalling, which in combination leads to insulin

resistance (Lau & Teoh, 2013). In addition, production of some glucose-regulating hormones occurs in adipose tissue, which, when in excess, can lead to increased hormone production and further insulin resistance (Thevenod, 2008).

Once diabetes has developed, risk of myocardial infarction and cerebrovascular accident increases by at least double (Lau & Teoh, 2013), as well as microvascular complications - commonly retinopathy, neuropathy, and nephropathy. Twenty years after onset, 80% of those with T2DM will have developed microvascular complications (Neff & le Roux, 2013). The development of atherosclerosis incurring further medical complications is linked to a decreased life expectancy of 10 years or more (Lau & Teoh, 2013).

Because of the severity of these complications, diabetes requires intensive and potentially expensive management. A US study in 2013 collated costings data from the range of aspects involved in diabetes care (Zhou, Zhang & Hoerger, 2013), and concluded that mean lifetime cost of diabetes management was around \$85, 000 (£50, 000) per person, which combined the costs of direct care including medication and input from healthcare professionals, and the indirect cost of treating macro- and microvascular complications. However, lifetime cost depended on age of onset – with those diagnosed at a younger age having a higher lifetime mean cost. Gender also played a role: women were found to have a slightly higher mean lifetime cost of diabetes, which the authors attribute to their longer life expectancy. In addition diabetes has an impact on the wider economy through absenteeism and inability to work through comorbidity-related disability (Yang et al., 2013).

The number of people with diabetes in the UK is currently predicted to increase to over 3.6 million by 2035 (Guariguata et al., 2014), and with it the financial burden to health and social services. The UK cost in 2010/11 of T2DM was estimated at £21.8 billion, including direct

medical care and wider costs: this is estimated to rise to £35.6 billion by 2035/36 (Hex, Bartlett, Wright, Taylor & Varley, 2012), an increase of 63%, and a proportionate rise from 10% of NHS outgoings to 17%. These estimates have been based on the assumption that costs of care are not altered considerably – although it is possible that treatment options such as medications become available which are cheaper or more effective, or changes to standards of care or the structure of the NHS affecting diabetes outcomes. Guidance for recommendations to care continue to evolve: the American Diabetes Association [ADA] updated their guidance this year (American Diabetes Association, 2014), and the National Institute for Health and Care Excellence [NICE] is reviewing clinical guidance for UK practice, to be published in 2015 (NICE, 2014).

Diabesity

‘Diabesity’ as a term to define the co-occurrence of T2DM and obesity has been used in scientific literature since the 1970s (Colagiuri, 2010) and 1980s (Bierman, 1983). It has even been proposed that T2DM be renamed ‘obesity dependent diabetes mellitus’ (Astrup & Finer, 2000) because of the close link between the aetiologies.

It has been discussed that obese patients with T2DM may traditionally have been given inadequate treatment options considering both conditions concurrently: obese patients at risk of diabetes may be screened for diabetes infrequently, and once diagnosis has been made pharmacological options may favour weight gain in already obese patients (Haslam, 2010). Some pharmacological choices can favour weight loss; a weight loss of 0.6kg to 3.5kg is anticipated using metformin, and 1.8 to 6.0kg using GLP-1 (glucagon-like receptor peptide-1)

receptor agonists. However sulphonylureas, insulin, TDZs (thiazolidinediones) and meglitinides all favour weight gain – up to 5.0kg, 4.0kg and 1.8kg respectively (Lau & Teoh, 2013).

Trends in treatment choice have changed over time. Between 1996 and 2005 the proportion of those with T2DM on insulin remained stable, the proportion of those on sulphonylureas decreased dramatically with a comparable increase in metformin and TDZ use (Gonzalez, Johansson, Wallandar & Rodriguez, 2009). Reasons for the changing trends are unknown, although drug costs, increased understanding and knowledge, or guideline priorities may be contributory factors. Treatment priorities for diabetes may also be affected by Quality Outcome Framework [QOF], as General Practitioners are financially incentivised to monitor and manage HbA_{1c} closely, but do not have the same motivation to consider their patients' obesity to the same degree (NHS Employers, 2014).

The nature of T2DM is that it is progressive as pancreatic β -cell function decreases (Kahn, Cooper, & Del Prato, 2014). Therefore, in order to maintain glycaemic control over time, an increased amount and types of medication may be required (Colagiuri, 2010), increasing the likelihood of weight gain.

In addition, patients may not always have an understanding of the weight management challenges posed by some of the antidiabetic medications, or the importance of weight management in T2DM treatment – and in one US based study of patients' perception of their T2DM management found that weight management advice is followed most often when clinicians raise it as an issue consistently at appointments with specific points of advice (Polonsky, Fisher & Hessler, 2010). It also found that even in very obese patients, some

reported that their diabetes clinicians had never raised the issue of weight management with them.

Dietary management of obesity and type 2 diabetes

It has been established for many years that people who are obese can improve health risks such as blood pressure, glycaemic control and lipid profile by losses of 10% starting body weight (Goldstein, 1992). However in studies of T2DM patients, weight losses of just 3% can incur meaningful benefit to these factors (Lau & Teoh, 2013) so long as this loss is maintained. Current guidance in the UK suggests patients should aim for 5 to 10% (NICE, 2009) concurrent to US guidance recommending 7% (Lau & Teoh, 2013).

However it has been observed that people with T2DM can find weight loss harder than those without (Norris et al., 2005), which is thought to be a dual effect of hyperinsulinaemia and hypoglycaemia. Insulin resistance leading to elevated insulin levels acts to inhibit lipolysis and therefore favouring fat storage. In addition hypoglycaemia incurred through the use of some medications can lead to unplanned food intake (Lau & Teoh, 2013).

UK guidance on weight loss in people who are overweight or obese recommends dietary intervention, behavioural change and physical activity as integral to any input (NICE, 2006). Dietary guidance for T2DM is healthy eating with a focus on balance across the food groups and reduction in salt, fat and sugar (Diabetes UK, 2012a; NICE, 2009). For weight loss, creating an energy deficit is recognised as being more important than macronutrient composition, in part due to the limited high quality evidence (Diabetes UK, 2011; Nield et al., 2007).

However, it has been noted that for people with complex conditions such as T2DM, multiple demands on the patients already exist, such as attending regular appointments, taking blood glucose readings, administering medications. Although encouraging multiple behaviour changes across diet, lifestyle, and physical activity is more effective than individual strategies for sustaining T2DM, research has shown that patients comply with achieving single behaviours more ably than an integrated approach (Wing et al., 2001).

Innovative dietary strategies have been proposed for T2DM management, and research into ways of achieving optimum weight loss and glycaemic and lipid control is ongoing.

Low fat diets

The Look AHEAD (Action for Health in Diabetes) trial (Wing et al., 2010) implemented all three recommended aspects of diet, physical activity and behavioural change in their intervention group, compared to the control group receiving standard treatment. This US-based randomised control trial included 5145 overweight or obese adults with T2DM between the ages of 45 and 75 years old. The intervention was based on individualised calorie restriction with fat <30% and protein >15% energy. Participants were given portion controlled plans and the option of meal replacement drinks to improve adherence if needed. They were supported throughout the four-year period, more intensively during the first year then receiving contact every two weeks, including face-to-face sessions and by telephone, and were weighed regularly. Compared with the control group who received standard care of three group sessions a year, the intervention group had lost significantly more weight after four years (mean 6.15% loss compared to 0.88% loss, $p < 0.001$), and also showed significant reduction in HbA_{1c} ($p < 0.001$) and trends towards improvement in blood pressure ($p < 0.001$ systolic, $p = 0.1$ diastolic). These effects were not linear: weight loss, increased fitness and decreased HbA_{1c}

was most marked at the end of the first year's more intensive phase, before rebounding slightly.

Other research has been on a much smaller scale. One six-week study of only 11 participants found that even ad libitum, low fat (<20% energy) diets could induce weight loss in the short term (6 weeks) without detrimental effect to lipid profile or glucose level (Gerhard et al., 2004). Another 40-week study randomised 79 people with T2DM who were overweight or obese into following diets focusing on low-fat (<30% energy) or low-glycaemic index. Both groups were calorie-restricted and involved exercise input and behavioural intervention (Fabricatore et al., 2011). Both groups lost weight: 4.5% and 6.4% starting body weight respectively. However, the difference lost between the groups was not significant ($p=0.28$), suggesting both as successful weight loss strategies.

High protein, lower carbohydrate diets

High protein diets are known to have short-term success in promoting weight loss in the general population (Clifton, Condo & Keogh, 2014). The New Zealand based DEWL (Diabetes Excess Weight Loss) trial compared a higher protein, lower carbohydrate diet with the higher carbohydrate diet in line with current guidelines, in 419 overweight or obese participants with T2DM (Krebs et al., 2012). In both groups, patients were assigned individualised calorie restricted plans based on 500 calorie deficit/day, and were supported by regular group sessions over the first year, which incorporated regular weighing and behavioural change input.

Over the two years, the high-protein and high-carbohydrate groups both lost weight, (mean 3.8% and 5.9% of original body weight respectively), and saw similar attrition rates (30.4%

and 28.9% of original cohort), indicating similar acceptability levels of conforming to the dietary requirements of the study. The energy balance of the high-protein diet was designed to be 30% protein, 40% carbohydrate and 30% fat, and the high-carbohydrate diet 15% protein, 55% carbohydrate and 30% fat. However by the 24-month point both groups had tended towards a mean diet similar to the reported baseline nutrient balance rather than the prescribed balance. The authors comment that this may reflect wider difficulties in sustaining dietary change.

Dietary compliance may also be confounded through the self-reported diet diaries which were used to assess nutrient balance. Underreporting in food diaries is common, in particular in those who are obese (Kretsch, Fong & Green, 1999). Notwithstanding this, both groups succeeded in long-term weight loss, and both groups experienced a similar degree of attrition. It is possible that the common factors including dietary advice, regular input and weighing may have contributed to the success of both groups, irrespective of intended dietary balance. It may also be a contributing factor to the success of the intensively treated group in the Look AHEAD study compared to the control group. A review of higher protein, lower carbohydrate diets concluded that the long term weight loss outcomes compared to the conventional healthy approach are similar (Dyson, 2014).

The findings of the DEWL study concur with the findings of a smaller US-based 12 month study, which randomised 105 participants into high-protein (20-25g carbohydrate) or low-fat (<25% energy) diets (Davis et al., 2009). Similarly, both groups lost similar amounts of weight by the twelve-month point (mean 3.1kg in both groups), and saw comparable rates of attrition (overall attrition 19%, arms reported to have 'similar' attrition, not specifically noted). This study also noted a lapse from the prescribed macronutrient balance. The authors discuss the

racial and cultural variation within their study groups, and suggest that the high number of black and Hispanic participants (which combined made up 80% of the cohort) may have found the macronutrient balances harder to achieve compared to the composition of their usual diets.

Neither DEWL nor the smaller US study saw any notable decreases in HbA_{1c}. However, Davis et al (2009) specifically reported reductions of antidiabetic medication in anticipation of decreased needs according to the assigned dietary arm, which may have impacted on glycaemic control and masked any benefit to HbA_{1c}. DEWL did not report whether any changes to medications were made. In contrast, a meta-analysis of older, smaller, shorter-term studies comparing low carbohydrate diets with higher-carbohydrate found that decreases in HbA_{1c} were linked ($p=0.013$) with lower proportion of carbohydrate (Kirk et al., 2008). The meta analysis discussion acknowledges that weight loss itself can reduce HbA_{1c} as an additional confounding factor.

The American Diabetes Association (2013) notes the recommended requirement of carbohydrate is a minimum of 130g/day to supply the nervous system, and the tendency of carbohydrate-rich foods in also containing necessary vitamins and minerals.

Meal replacement diets

Meal replacement diets are often used to form very low calorie diets (VLCDs), which NICE defines as <1000 calories/day (NICE, 2006). A 2005 Cochrane review of weight loss interventions in T2DM found VLCD a successful strategy as part of multifaceted approach (Norris et al., 2005). More recently, in very small scale non-randomised studies, VLCD meal replacement programmes have shown effective in short-term diabetes management. In UK

research of a small sample of 11 subjects, rigorous dietary restriction over an 8-week study period demonstrated normalisation of glycaemic control in all patients, compared to a non-T2DM control group of similar anthropometry. The subjects consumed meal replacement drinks, supplemented with vegetables to the combined value of 600 calories (Lim et al., 2011). The cohort were overweight or obese at start (mean 33.5 kg/m²), weight loss over the 8 week study period was mean 15.3kg (15% mean starting body weight). Fasting glucose of the diabetes cohort had become not significantly different to the non-diabetes cohort within the first week of the diet ($p=0.18$), and HbA_{1c} had decreased to become not significantly different to the non-diabetes cohort by the eighth week ($p=0.27$).

The diabetes cohort was provided with information about healthy eating and portion control to support them post-research, and twelve weeks after the end of the study, three of the eleven participants had returned to being classified as having diabetes. Mean weight gain was 3.1kg, and mean fasting glucose had significantly risen since the endpoint ($p<0.01$). No longer term follow-up assessed the effectiveness as a sustainable strategy for diabetes treatment. Furthermore, all the participants had been diagnosed less than 4 years prior to the study, and were either treated by diet alone or by metformin or sulphonylureas. These medications were stopped prior to the commencement of dietary restriction, to avoid confounding the results, and it is not reported whether these required recommencement in the months following the trial.

This study was followed by another equally small British study (Hookey, O'Shea, Freeman & Collins, 2014) which added a psychological component to an eight-week meal replacement diet, consisting of 600 calories from meal replacement drinks and 200 calories from additional vegetables. Again all subjects had been diagnosed with diabetes within the 4 years previously,

and were all obese (mean BMI 38.4 kg/m²). Psychological input occurred in five group sessions per week for the first two weeks, and subsequently twice a week for six weeks. This study also looked at outcomes 3 and 12 months after the start of the study.

Mean weight loss over the 8 weeks was 16.6kg (14.7% mean starting weight). Significant decreases to HbA_{1c}, cholesterol, and glucose level were seen at the end of the intervention ($p<0.001$, $p<0.0001$, and $p<0.002$ respectively), but by the three months point only HbA_{1c} was significantly different to starting level ($p<0.002$), and this effect was not seen by 12 months. However, the weight loss was better sustained – a mean of 2.0kg regained by the three month mark. Drop out by 12 months was high (only 4 of the original 11 participants remained), but mean loss at that point was 9.3kg. The authors of this study note that comparison with the original 2011 study is limited because of its lack of published follow-up, and because of its own high drop-out rate at 12 months. Therefore the benefit of the additional psychological input is unclear quantifiably. In feedback questionnaires, however, participants reported finding this element useful, both for the peer support of the groups and the psychological strategies.

Intermittent fasting

Intermittent fasting (restricting calories on some days of the week and eating ad libitum for the remainder) as a weight-loss method has become a popular strategy in the general population. Compared to moderate daily calorie restriction, intermittent fasting has been shown in a review of studies comparing both (Varady, 2011) to be as effective at weight loss, and may confer an advantage in preserving fat free mass during weight loss. Research involving those at high risk of developing diabetes indicate that intermittent fasting may be of benefit in preventing the onset of diabetes (Barnosky, Hoddy, Unterman & Varady, 2014).

The use of intermittent fasting in those who have developed diabetes is proposed as an area for future investigation (Brown, Mosley & Aldred, 2013). Public health guidance cautions those with diabetes from undertaking intermittent fasting (NHS Choices, 2013), especially those taking insulin (Patient UK, 2014). Longer-term studies into the efficacy of intermittent fasting has not been explored (Dyson, 2014).

Qualitative changes to diet

There is also a strong body of evidence that qualitative dietary changes independent of weight loss are also beneficial to management of T2DM (Annuzzi, Rivellese, Bozzetto, & Riccardi, 2014). Reduction in saturated fatty acids and an increase in monounsaturated fatty acids, a decrease in salt intake, and a focus on consumption on low glycaemic index, have all been found across studies to improve the health markers of insulin resistance, hypertension, and dyslipidemia. The reviewers suggest that qualitative changes may be more sustainable than maintaining weight loss, although they provide no evidence to support this claim.

Bariatric surgery

Bariatric surgery as a weight loss treatment option also improves glycaemic control in diabetes, in addition to promoting and maintaining higher levels of weight loss than dietary or pharmacological treatments can offer (Lau & Teoh, 2013). Both weight loss expectation and degree of diabetes remission varies by procedure and length of time since the diabetes diagnosis (Dixon, Zimmet, Alberti & Rubino, 2011). Bilio-pancreatic diversion can be expected to induce 73% excess weight loss, with 95% of diabetes in remission after two years. The roux-en-Y bypass and gastric band typically results in 63% and 49% of excess weight loss

respectively, and remission of 80% and 57% diabetes at two years respectively (Dixon, Zimmet, Alberti & Rubino, 2011).

Although diabetes remission is thought in the long-term to be a primarily a consequence of weight loss, early improvements in glycaemic control prior to substantial weight loss occurring is seen more in diversionary procedures, hypothesised to be related to changes to gut hormones (Dixon, Zimmet, Alberti & Rubino, 2011). Two primary theories have been proposed: the first suggests that as food reaches the small intestine more quickly during digestion, in turn increasing the release of glucagon-like- peptide-1 (GLP-1) into the gut (Mingrone & Castagneto-Gissey, 2009), this then stimulates insulin secretion and removes glucose from the bloodstream (Rubino, 2008). The second suggests that diversion of food away from the upper part of the small intestine results in decreased release of anti-incretin hormones (which blunt the insulin response), thereby improving glycaemic control (Mingrone & Castagneto-Gissey, 2009). It is thought that the former is more likely, as little is known about anti-incretin hormones (Rubino, 2008).

A US retrospective cohort study of gastric bypass patients found that of the 4434 with diabetes who underwent surgery, 68.2% experienced initial remission, of which 35.1% saw re-emergence of diabetes within 5 years (Arterburn et al., 2013). However, it is recognised that long-term follow-up of bariatric patients across all procedures is currently limited (Lau & Teoh, 2013), including the lifelong nature of bariatric surgery on diabetes reoccurrence.

Bariatric surgery may also aid improvement to microvascular complications, although the evidence is limited (Neff & le Roux, 2013). Any benefit to diabetic nephropathy following surgery is unknown and it is suggested that it would be confounded by the potential onset of nephropathy due to micronutrient deficiency, which can occur after bariatric surgery due to

high alcohol consumption or non-compliance with micronutrient supplementation. A review of the available evidence suggests that retinopathy improves following bariatric surgery, and can help to delay onset in those at risk, although specific control trials to quantitatively assess the role of surgery in retinopathy are needed. For those with moderate kidney disease, function can be maintained or improved by surgery. Those with more severe nephropathy are often precluded from bariatric surgery because of the perceived surgical risks, although it is thought that the surgery may in fact improve renal function.

Despite the limited long-term follow-up, guidelines are currently being drafted recommending bariatric surgery as a treatment option for those diagnosed with T2DM within the last 10 years, and a BMI $>30 \text{ kg/m}^2$, or lower in those of Asian origin. This compares with current guidance advising that surgery be considered as an option for those with T2DM and a BMI $>35 \text{ kg/m}^2$ (NICE, 2014a). There are additional considerations to bariatric surgery: the provision of specialist surgical facilities, psychological readiness to adapt to post-operative dietary restrictions, ability to attend multiple and long-term follow-up, and the risk of needing revisional procedures at a later stage (NICE, 2006).

Guidance is not necessarily implemented at local level, however the change in guidelines may in part reflect the increased understanding of the benefits of bariatric surgery in diabetes treatment.

Multifaceted diabetes services

In response to the comorbid rise of diabetes with obesity, multidisciplinary diabetes services have in some places been piloted, for those with or at risk of developing T2DM. The Mid

Yorkshire NHS Trust has developed an approach which seeks to improve obesity and diabetes outcomes together. The team includes a consultant, diabetes specialist nurse, psychologist, dietitian, physiotherapist and occupational therapist (Rajeswaran, Pardeshi, & Srinivasan, 2012). The dietitian, psychologist, physiotherapist and occupational therapist are able to implement the dietetic, behaviour change and physical activity aspects of improved management, with the consultant and diabetes specialist nurse focusing on pharmacological considerations, blood test results and any other comorbidities, such as sleep apnoea or hypogonadism.

The twelve-week group programme piloted by Mid Yorkshire NHS Trust shows successful short-term outcomes. Retention rate amongst the 143 adults was 90%. Mean weight loss was 3.6% in the 12-weeks, and up to 40% of the participants who had enrolled on the programme with a view to bariatric surgery had changed their mind about being considered (Srinivasan, 2014). The dietetic strategies employed on the programme were not reported. However, as previously discussed the support and regular input surrounding the dietetic care may have contributed as influentially as the dietary guidance.

The retention rate of 90% compares favourably with other standard weight management programmes. In a review of 25 studies reporting weight management service outcomes, between 13.4% and 80% attrition was observed (Miller & Brennan, 2014), although what was defined as 'attrition' varied between studies: in some studies it was attending fewer than a set proportion of appointments, whereas in others it referred to those who failed to attend by the end-point. It has been suggested that poor early weight loss may increase risk of consequent drop-out in weight management services (Miller & Brennan, 2014). Patients in the Mid Yorkshire programme received intensive and regular input (Srinivasan, 2014),

enabling the team to identify those at risk of reduced weight loss, and possibly minimise attrition.

In addition, the programme focuses strongly on self-management (Rajeswaran, Pardeshi, & Srinivasan, 2012). In a US survey of overweight and obese T2DM patients, weight loss was more successful in those with greater understanding of the role of weight management in their T2DM control (Polonsky, Fisher & Hessler, 2010).

The benefit of lifestyle modification programmes as a lifetime strategy for diabetes has been disputed, with long-term weight regain and consequent decreased glycaemic control often occurring (Colagiuri, 2010). The Mid Yorkshire pilot does not report whether they will be following up their participants long-term, but did invite completers to return after a year for further input if necessary (Srinivasan, 2014).

Conclusion

Both bariatric surgery and multifaceted diabetes services offer promising solutions for the increasing burden of diabetes in the UK. However, this literature review has also seen that there are other opportunities, and challenges to be met, in tackling diabetes in the UK and internationally.

The increasing research into innovative pharmacotherapies for diabetes management recognises the need to control glucose levels without the side effects of weight gain or risk of hypoglycaemia (Verspohl, 2012), potentially decreasing the challenges of weight loss for the future. In addition, a larger scale UK-based study utilising meal replacement VLCDs in T2DM has been funded to build on the preliminary trials discussed, using a larger cohort in the real-

life setting, and comparing with currently available standard diabetes management (Diabetes UK, 2014).

Emphasising to patients the central importance of weight management as treatment for T2DM may influence motivation to persevere at weight loss (Polonsky, Fisher & Hessler, 2010). In addition, trial conditions may not reflect applicability to real life settings, and the facilities and service provision are unlikely to be practicable at local level. Studies comparing dietary balance observed that the regular input and support may be of as much benefit to weight loss as optimising dietary input specifically to T2DM (Krebs et al., 2012; Davies et al., 2009). Therefore, in the absence of multifaceted diabetes services, it is feasible to suggest that a local specialist weight management service may be able to benefit T2DM patients.

Yet in light of the current challenges to weight loss discussed in this review (Lau & Teoh, 2013; Haslam, 2010), it is unclear how outcomes for those with T2DM compare with non-T2DM counterparts receiving the same pathway of care. In light of the rising costs of diabetes (Zhou, Zhang & Hoerger, 2013; Hex, Bartlett, Wright, Taylor & Varley, 2012), assessing the effectiveness of existing locally available services in T2DM management may provide valuable insight in establishing what complementary service provision is required.

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Differences in outcomes between type 2 diabetes and non-type 2 diabetes patients in a
local specialist weight management service

Rationale for journal choice: Journal of Human Nutrition and Dietetics

Journal of Human Nutrition and Dietetics is a peer-reviewed journal publishing work in the area of dietetic practice. As it is the journal of the British Dietetic Association, the subject matter will be relevant to many of the primary readership working in similar clinical settings. It is also likely to attract readers of other professions of the multidisciplinary team, such as GPs, diabetes specialist nurses, diabetologists and practice nurses who are seeking evidence around the role and effects of dietetic intervention.

Abstract

Background: Being overweight or obese is known to increase risk of type 2 diabetes (T2DM), and as obesity levels have risen nationally, levels of T2DM have also increased. Conversely weight loss has long been recognised as an effective strategy for improving management of T2DM, although it is acknowledged that weight loss in T2DM may be slower. It is recommended that obese people with T2DM are provided with appropriate support. In a local dietetics department this is via a Specialist Weight Management service.

Study Aim: To compare outcomes between patients referred to the service with a diagnosis of T2DM compared to those without, and outcomes of those with T2DM by treatment type.

Methods: Data from NHS Trust care records from 231 patients referred into the service over a six month period was used to evaluate weight loss in those with and without a diagnosis of

T2DM. Changes in food frequency scores and metabolic output were also compared. Of those with T2DM, patients were grouped by pharmacological treatment type to compare outcome.

Results: There were no significant differences between the two groups at the starting point, with regard to mean weight or BMI, or reported food frequency score or metabolic score. Both groups showed significant mean weight loss, and there was no significant difference between the two groups. Significant improvements to reported food frequency and metabolic output scores were seen in the non-T2DM group, but not the T2DM group. However, high attrition was seen in both groups, therefore the pharmacology subgroups were small and statistical analysis was not viable.

Conclusion: A local dietetic weight management service can successfully effect weight loss as part of the management of obese T2DM patients.

Key words: type 2 diabetes, obesity, weight management, dietary intervention

Introduction

Clinical Background

Type 2 diabetes (T2DM) is on the rise in Britain (Diabetes UK, 2012), primarily as a result of increased obesity rates (Abdullah, Peeters, de Courten & Stoelwinder, 2010). T2DM can have considerable impact on health including cardiovascular complications and decreased life expectancy (Lau & Teoh, 2013). Lifelong management of diabetes is expensive (Zhou, Zhang & Hoerger, 2013), although modest sustained weight loss in those carrying excess weight can improve diabetes control (Lau & Teoh, 2013). Diabetes patients are often referred to weight management services, however weight loss in those with diabetes is often found to be slower than in their counterparts without diabetes (Lau & Teoh, 2013; Norris et al., 2005).

In part this is thought to be due to the challenges posed by diabetic medication, some of which favour weight gain (Haslam, 2010). This can be compounded over time as the disease progresses (Kahn, Cooper, & Del Prato, 2014), increasing likelihood of needing more types of medication (Colagiuri, 2010) in order to maintain control.

Review Question

This study compared outcomes between patients with a diagnosis of T2DM and those without, who participated in a local specialist weight management service. The outcomes considered were:

- Change in weight, and consequently to body mass index (BMI)

- Changes in reported metabolic output
- Changes in food frequency questionnaire score

Among those diagnosed with T2DM, comparisons were further made in outcomes according to treatment category.

Context

The dietetic department at Warrington and Halton Hospitals NHS Trust provides a specialist weight management service to obese patients living in the Halton area, including those with complex medical conditions, and those wishing to be considered for bariatric surgery. The service offers dietetic support to patients at regular intervals for up to two years. In addition, patients requiring specific support can access specialist cognitive behavioural therapy via referral from the dietitian. Patients may also attend a group programme of nutrition education and exercise, which is open to all overweight adults who are fit enough to participate in the exercise session.

Patients attending the weight management programme are formally assessed at their initial appointment, and again after 6, 12, 18 and 24 months. The assessed outcomes include physiological measures of weight and BMI changes, and lifestyle measures of reported food frequency questionnaire and metabolic output reported scores (APPENDICES A&B).

It is known that weight loss efforts transition towards weight maintenance after six to nine months after commencing weight loss treatment (NICE, 2006). Therefore this review will focus on outcomes occurring during the first six months of treatment within the specialist weight management service.

Methods

Participants All patients referred to the Specialist Weight Management service between 1st June 2013 and 31st December 2013 were considered for inclusion. Their data was accessed through the department's database, DWARF. Participants are detailed in Figure 1.

Pregnant patients were excluded because of the confounding effect of pregnancy on weight. Any patient who did not have a diagnosis of T2DM at their initial assessment but went on to develop it within the 6 months was grouped with those without a diagnosis of T2DM.

Consent was granted by Warrington and Halton NHS Trust to use the data in anonymised format for the purposes of this service review (APPENDIX C). The proposed evaluation was given ethical approval by the University of Chester Ethics Committee before it was conducted (APPENDIX D).

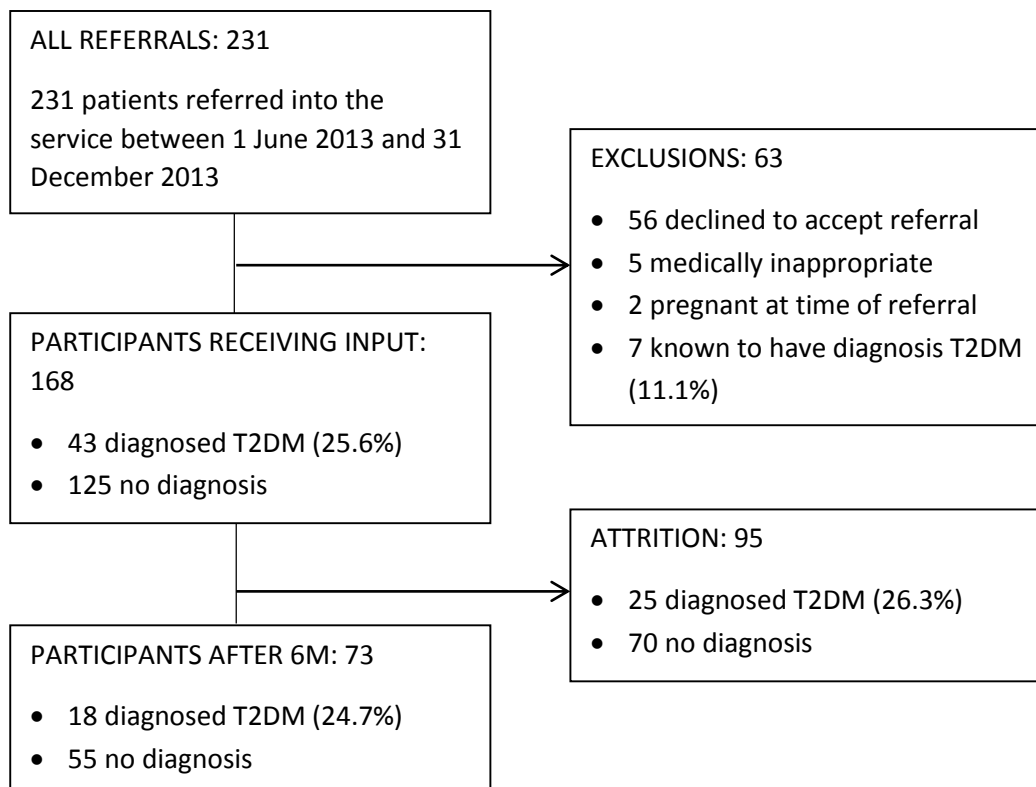


Figure 1: participant inclusion process

Research Design The study used a retrospective cohort design. Patients were only selected for the service review based on the date on which they were referred into the Specialist Weight Management service, no other inclusion criteria were applied. All data had already been collected; no intervention was specifically implemented on this cohort of patients aside from standard care provision.

Measurement procedures Data for each patient was collected from the paper documentation recorded at the time of each point of contact, and transferred anonymously to SPSS version 21.0. Height was recorded to the nearest centimetre from GP records or as assessed by health trainer – and was assumed to remain constant over the duration of the intervention. Weight was read to the nearest 0.1kg on calibrated scales at each dietetic appointment, with patients wearing light clothes. Food frequency and metabolic output were self-reported by

participants who were asked questions verbally by the dietitian during the relevant appointments (APPENDICES A&B). Diagnosis of T2DM, and medications, were detailed on the referral documentation, or self-reported by the patient and noted on the care record (APPENDIX E).

Those with T2DM were categorised further into: no diabetes medication (treating with diet and lifestyle only); those on monotherapy; those on multiple medications but not insulin; and those on multiple medications including insulin.

Data analysis

Data was input in anonymised format to a Microsoft Excel spreadsheet. Those who dropped out were then removed from the spreadsheet, and further basic analysis used to calculate changes in outcome measures (weight, BMI, food frequency score and metabolic equivalent) on the remaining subjects. At this stage information was transferred to SPSS version 21.0 for comparative statistical analysis between the diabetes and non-diabetes groups.

Comparing between T2DM and non-T2DM groups, the distributions did not meet the Shapiro-Wilk statistic for normality (either or both groups showed $p < 0.05$ in all comparisons). Therefore a Mann-Whitney U test was conducted for each.

Comparing between T2DM and non-T2DM groups, the distribution for starting FFQ score and changes to FFQ score met conditions for normality and homogeneity of variance, and an independent t-test was conducted for each.

The distributions for starting metabolic output score, and changes to metabolic output score, did not meet the Shapiro-Wilk for normality (one or both groups showing $p < 0.05$). Therefore a Mann-Whitney U test was conducted for each.

The significance of changes to weight, food frequency score and metabolic output score was assessed for both T2DM and non-T2DM groups. Weight changes in both groups did not meet the Shapiro-Wilk statistic for normality (either or both groups showed $p < 0.05$) and a Wilcoxon test was conducted. Likewise, metabolic output score changes in both groups did not meet the Shapiro-Wilk statistic for normality (either or both groups showed $p < 0.05$) and a Wilcoxon test was conducted for both T2DM and non-T2DM subgroups.

Food frequency score changes in both groups met conditions for normality (both groups showed $p > 0.05$) and a paired t-test was conducted for both T2DM and non-T2DM subgroups.

Results are presented as: Mean (Standard Error). Statistical significance is accepting at $p < 0.05$.

Results

Of patients who were seen for at least one appointment, mean starting BMI was 39.2 kg/m²; 78.5% female, 21.5% male.

Physiological outcomes

The comparison between physiological outcomes are shown in Table 2

Table 2: Comparison of physiological outcomes between diabetes and non-diabetes groups over six months

	T2DM (n=18)	No T2DM (n=55)	P
Starting weight (kg)	120.11 (8.38)	112.73 (3.48)	0.586
Weight change (kg)	-4.26 (1.27)	-3.76 (0.92)	0.582
Starting BMI (kg/m ²)	42.97 (2.57)	41.31 (1.10)	0.888
BMI change (kg/m ²)	-1.51 (0.49)	-1.41 (0.33)	0.683

Lifestyle outcomes

The comparison between lifestyle outcomes are shown in Table 3.

Table 3: Comparison of lifestyle outcomes between diabetes and non-diabetes groups over six months

	T2DM (n=18)	No T2DM (n=55)	P
Starting FFQ score	27.3 (1.61)	25.6 (0.83)	0.331
Change to FFQ score	3.53* (1.89)	3.86^ (0.77)	0.846
Starting metabolic output	521.9 (275.5)	553.3 (136.9)	0.354
Change to metabolic output	29.9* (239.6)	489.8 [§] (126.2)	0.115

*n=17, ^n=51, §n=52

Comparison between pharmacotherapy treatment amongst the diabetes group

Only 18 patients with diabetes received treatment to six months, distribution shown in Table 4.

Table 4: distribution of T2DM patients by pharmacotherapy treatment

	Number of patients	Mean start weight (kg)	Mean weight change (kg)	Mean start BMI (42.3kg/m ²)
Diet only	3	129.1	-5.8	42.3
Monotherapy	8	121.0	-4.8	46.1
Multiple therapies (not including insulin)	5	116.9	-4.8	39.2
Multiple therapies including insulin	2	111.3	1.6	40.7

Because of the small subgroup size, an ANOVA to compare the groups statistically was not possible, although the descriptive statistics suggest that treatment involving more medications may be linked with less weight loss.

Table 5: statistical significance between starting and six-month data

		Start	6M	change	P
T2DM (n=18)	Weight (kg)	120.11 (8.38)	115.9 (8.14)	-4.26 (1.27)	0.007
	FFQ	27.3 (1.61)	30.2 (1.15)	3.53* (1.89)	0.08
	Mets	521.9 (275.5)	522.8 (150.1)	-29.9* (239.6)	0.463
No T2DM (n=55)	Weight (kg)	112.73 (3.48)	109.0 (3.76)	-3.76 (0.92)	0.0001
	FFQ	25.6 (0.83)	29.5 (0.80)	3.86^ (0.77)	0.0001
	Mets	553.3 (136.9)	1073.6 (162.5)	489.8 [§] (126.2)	0.0001

*n=17, ^n=51, [§]n=52. FFQ= food frequency questionnaire score, Mets = metabolic output score

Discussion

Outcomes of the service in general

Both T2DM and non-T2DM groups lost a significant amount of weight. Other studies have found comparable weight loss. A similar NHS-funded programme in Shropshire evaluated weight loss in 1129 participants, and found that men and women lost mean of 5.7 and 4.2kg over twelve weeks (Bhogal & Langford, 2014). They observe that the men may have lost more due to having a higher starting body weight (mean 113.4kg compared to 94.9kg women). The

authors do not comment whether the weight loss between the two genders is significantly different; in this study although there was no statistical difference between the amount of weight lost between the groups, T2DM group had a slightly higher starting mean weight, and a slightly greater mean weight loss. However decreases in BMI were not statistically different between the two groups.

At the start point, metabolic output was not significantly different between the two groups (Table 3). However, metabolic output increased significantly in the non-T2DM group over the six months, but not in the T2DM group (Table 5). Regular physical activity is recommended to improve health markers as well as improve weight loss (Myers, 2003). In addition, evidence from people who have successfully maintained weight loss report that the majority increased their physical activity whilst losing weight, and still undertake daily physical activity (National Weight Control Registry, n.d.).

Likewise, starting food frequency score was not significantly different between the two groups (Table 3), and the increase in the non-T2DM group was significant after six months, compared to a non-significant change in the T2DM group (Table 5). The questionnaire used was designed specifically for this weight management service, and is therefore not directly comparable with other studies. However the key aspects demonstrated by the food frequency questionnaire of regular and balanced eating are considered the primary steps in recommended dietetic practice (Grace, 2011).

The gender balance (78.5% female, 21.5% male) of attending participants in this study is seen elsewhere. The Shropshire weight management programme observed that their intake showed a greater proportion of women than men (71.9% female, 28.1% male) (Bhokal & Langford, 2014), although both men and women lost weight and sustained their losses. Even

in the male-oriented environment of US military veterans, women are disproportionately represented in their weight management programme: only 5.5% of military veterans are female, but 14% of the 18, 865 participants were female (Spring et al., 2014). It is not discussed whether this is because these females are disproportionately aware of the importance of weight management, or because females are disproportionately likely to be overweight than their male counterparts.

It is also not known whether patients were attending for support for the first time, or whether they had attended the Specialist Weight Management service previously. It has been observed that repeated intervention is likely to be of benefit to those who are obese (Spring et al., 2014). Locally, policy allows for patients to be re-referred to the Specialist Weight Management service after their two-year discharge point. However, as repeat patients may be seeking support with weight maintenance rather than weight loss, this may not accurately reflect overall weight loss, and these patients may be more likely to maintain lifestyle and activity behaviours, rather than seek to improve them further.

T2DM compared with non-T2DM

Despite the expectation that T2DM creates challenges to weight loss (Lau & Teoh, 2013), weight loss in the T2DM group was not statistically different to the non-T2DM group. However, improvements in reported food frequency scores and metabolic output were significant in the non-T2DM group compared to T2DM, which may be of relevance to longer-term outcomes. It is known that in encouraging behaviour change in other medical conditions, attempting engagement of multiple behaviour changes is less effective than focusing on one at a time. This may also hold true in T2DM, and depend on motivation behind wanting to engage in behaviours (Wing et al., 2001). For example, perceived risks of hypoglycaemia after

engaging physical activity, or from instigating a reduction in calories through carbohydrates, could be considered by the patient to outweigh the benefits in weight management, and limit their willingness to change in these areas.

Of those who received treatment in this service, 25.6% had a diagnosis of T2DM. This is above population average, but is anticipated given that obesity is the primary risk factor for onset of T2DM (Diabetes UK, 2012). In the area served by the weight management service, 7.2% of the local population (7,367) are known to have a diagnosis of diabetes (Public Health England, 2014). In previous years this locality has mirrored wider trends, with 90% of diabetes diagnoses being T2DM (NHS Information Centre, 2010). It is anticipated that this under-represents the total number of those with type 2 diabetes due to those who are undiagnosed (NHS Information Centre, 2010).

However, of the local T2DM population, the service is supporting a small proportion. Some T2DM patients may have declined input, be receiving weight loss support from a commercial provider or via the diabetes dietitian. Until recently, local patients were referred to the diabetes dietitian at initial diagnosis of T2DM, (97 referrals were made to the diabetes dietitian during January to June 2014) who would provide education and onward referral to the weight management service for any patients who were appropriate and accepted the referral. However, due to recent pathway changes all obese T2DM patients referred to dietetics are now seen by the weight management service as first line treatment.

Comparing Halton with the national picture, the proportion of T2DM patients receiving the full complement of recommended care processes falls in the second quartile, above average. In addition, those for whom cholesterol, blood pressure and HbA_{1c} targets are being met fall in the first centile, above average (NHS Information Centre, 2010). It is possible that clinicians

therefore do not feel the need to address obesity as an issue in patients already achieving good management markers, even at higher BMI.

Pharmacological Subgroups

No statistical analysis was possible with the small subgroups. A larger cohort would have presented the opportunity for further analysis. However, it is interesting to observe the spread of patients across the subgroups. Guidelines recommend instigation of pharmacotherapy in those for whom diet and lifestyle as first line treatment does not provide adequate control (NICE, 2009). Changes to the pathway provision may mean that in future more newly diagnosed patients at the 'diet only' stage of disease progression are seen by the weight management service.

Limitations

Several limitations of the study were identified. Primarily, the high attrition rate to the service of 56.6% reduced the number of participants whose 6 month data could be included. This trend is reported in cohort studies of other weight management services (Bhagal & Langford, 2014). Attrition rates from weight management services were studied in a large cohort of nearly 30,000 overweight and obese individual enrolled to services associated with the US military (Spring et al., 2014), who reported high drop-out rates in the early stages of intervention. They identified a number of factors associated with attrition rate. They found that those most likely to keep attending had a higher starting BMI, had more comorbidities, and were older.

They also found that local resources and facilities made a difference. Those who were offered a wider range of strategies (such as goal-setting, structured diet plans, physical activity, self-

monitoring, behavioural support) achieved a higher retention rate. Measuring these factors are outside the scope of this review, however this service is not alone in experiencing attrition of participants. The impact of attrition is not only on those who drop out, but affects the resources available to the continuing participants, incurs wasted administration costs, and limits the value of outcome data and the interpretation which can be drawn from them (Miller & Brennan, 2014).

Reasons for T2DM attrition has also been studied. A review evaluating why people with chronic illnesses fail to attend services included several studies of diabetes patients (Paterson, Charlton & Richard, 2010). Most consistently poor compliance of diabetes patients was related to high HbA1c, high blood pressure and high BMI. But those with fewer complications, and lack of perception of severity were also linked with poorer attendance. The authors of the review comment that if the clinician does not explain the relevance of their care they may not see the importance of coming back. It is also possible that if the referring clinician does not explain the reason for their referral, they may not feel the need to attend their first appointment. Non-attenders are not routinely followed-up to gain insight into why they choose not to continue with care, and up-to-date biochemistry is not always available to gauge whether the patient's efforts are impacting on health markers. However, it recognises the role of referring clinicians in emphasising the relevance of the referral and weight management in minimising attrition.

Limitations to the quality of the data also exist given the self-reported nature of the lifestyle outcomes: food frequency questionnaire scores are by their nature self-reported, and metabolic output was also self-reported. Food frequency questionnaires are known to have limited reliability when used as an isolated measure of food intake (Brown, 2006), and

although this questionnaire meets the commissioning body's requirements, it is not a validated tool. It is also possible that participants answered with bias, overestimating the quality of their lifestyle in order to avoid feeling that they will be judged by the dietitian.

Diagnoses and medications were in many cases self-reported, with potential for error of accuracy. It is also possible that, given the estimates of undiagnosed diabetes prevalence in the UK and locally (Shaw, Sicree & Zimmet, 2010; NHS Information Centre, 2010) an additional proportion of those considered not to have diabetes could have been diagnosed if tested at the time of referral. In addition, non-obesity related medications (commonly anti-psychotics and antidepressants) can confound weight loss in both groups (American Diabetes Association, American Psychiatric Association, American Association of Clinical Endocrinologists, & North American Association for the Study of Obesity, 2004; Patten, Williams, Lavorato, Khaled & Bulloch, 2011).

Recommendations for future research

Analysis of a larger cohort of patients would allow a more thorough assessment of this population. The current service provision has been offered since 2011, for which data is available. However, for the T2DM patients historic data may not reflect current practice (for example pharmacology pathways, provision of group education, dietary guidelines). With a larger cohort it would also be possible to compare outcomes for those who concurrently receive specialist weight management with active input from a diabetes professional, with those who are not receiving active input. Comparison with outcomes from the diabetes dietetic service would also be of benefit to ensure best and effective practice is being shared consistently.

In addition, in time longer-term (12 and 24 month) outcomes for the current cohort will be available, providing further insight into the service's effectiveness at weight maintenance stage as well as during the weight loss time frame. This may also contribute further to understanding the differences between lifestyle outcomes between T2DM and non-T2DM groups.

Currently, there are no specific outcome measures tailored to evaluate the impact of the weight management service on T2DM in that subgroup. Measures for consideration include most recent HbA_{1c}, fasting blood glucose, frequency of experiencing a 'hypo', perceived understanding and ability to manage T2DM. Comparing these outcomes with weight loss may inform whether weight loss and improved T2DM control are both achieved concurrently using the approaches available in this service, especially as weight loss appears to occur significantly before lifestyle patterns change. It may also serve to demonstrate the effectiveness of the service as an integrated part of the diabetes multidisciplinary approach.

As discussed above, provision of different aspects of weight management can improve retention rate (Spring et al., 2014), and some service factors are linked with attrition (Paterson, Charlton & Richard, 2010). This service is able to provide a number of aspects within the service, including: psychological input, exercise sessions, individualised portion plans, consideration for bariatric surgery, although patients may be only accessing those most relevant to them. Were a larger cohort available, analysis of retention and weight loss outcomes according to which aspects are accessed may be useful in determining where funding is most beneficially spent.

In particular, because bariatric surgery is becoming increasingly accepted as a beneficial treatment for diabetes remission prior to weight loss (Dixon, Zimmet, Alberti & Rubino, 2011),

it is not known whether the proportion of T2DM patients in this service seeking bariatric surgery reflects this, and the potential economic benefits of preparing and funding patients to undergo this process have not been evaluated.

Acknowledgements

Many thanks to Warrington and Halton NHS Trust dietetics department for allowing the service review to be conducted. In particular, to each member of the dietetic and administration teams for their practical advice, professional interest, and friendly encouragement.

Thanks are also due to the teaching and administration staff in the Clinical Sciences department at the University of Chester, for their academic wisdom and great patience. It has been greatly appreciated.

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APPENDIX A: Food Frequency Questionnaire

Name: _____

*Since you started the Fresh Start programme, has your mental health **Improved** or **Stayed the same**

TOTAL _

Initial	6 M	12 M	18M	Final

1. How often do you eat breakfast?

Every day (4)

Occasionally (once per month) (1)

4 - 6 times per week (3)

Never (0)

1-3 times per week (2)

Initial	6 M	12 M	18M	Final

2. How often do you miss meals?

Every day (0)

Occasionally (once per month) (3)

4 - 6 times per week (1)

Never (4)

1-3 times per week (2)

Initial	6 M	12 M	18M	Final

3. How many days last week did you eat fruit and/or veg?

Initial	6 M	12 M	18M	Final

0 (0)

1-2 (1)

3-4 (2)

5-6 (3) Daily (4)

4. How many portions of fruit and/or veg did you eat per day? (One portion of fruit is a medium size apple, banana, 12 grapes, 2 plums, 7 strawberries or 3 tablespoons tinned fruit)

Initial	6 M	12 M	18M	Final

0 (0)

1-2 (1)

3-4 (2)

5 or more (3)

5. How often do you eat fried food?
(Includes foods that are fried at home, e.g.
burgers,
sausages, chips, takeaways, fried chicken)

Initial	6 M	12 M	18M	Final

Every day (0)

Occasionally (once per month) (3)

4 - 6 times per week (1)

Never (4)

1-3 times per week (2)

Amount _____ Improvement over previous questionnaire (1)

6. How often do you snack on biscuits, cakes, sweets,
chocolate, ice cream, crisps, pastry, pies?

Initial	6 M	12 M	18M	Final

Every day (0)

Occasionally (once per month) (3)

4 - 6 times per week (1)

Never (4)

1-3 times per week (2)

Amount _____ Improvement over previous questionnaire (1)

- 7a. How many days of the week do you drink
alcohol?

Initial	6 M	12 M	18M	Final

0(4)

1-3 (3)

4-5 (2)

6-7 (1)

- 7b. How many units of alcohol do you drink per week?

(1 unit is $\frac{1}{2}$ pint beer/lager, 1 single pub measure of spirit, 1 small glass of wine)

Initial	6 M	12 M	18M	Final

Females: 0 (3) 1-7 (2) 8-14 (1)
>14 (0)

--	--	--	--	--

Males: 0 (3) 1-11 (2) 12-21 (1) >21 (0)

Amount _____ Improvement over previous questionnaire (1)

8. How often do you eat oily fish? (e.g. fresh tuna, salmon, mackerel, kippers, trout)

Two or more times a week (3) Once a week (2)

Initial	6 M	12 M	18M	Final

Less than once a week (1) Never(0)

9. Do you overeat when you are upset, anxious, worried, angry or depressed?

Always (0)
Often (1)

Initial	6 M	12 M	18M	Final

Sometimes (2) Never (3)

10. Do you overeat when you are bored?

Always (0)
Often (1)

Initial	6 M	12 M	18M	Final

Sometimes (2) Never (3)

11. Do you plan what you are going to eat?

Always (3)
(2)

Initial	6 M	12 M	18M	Final

Often

Sometimes (1) Never (0)

Fresh Start Programme

METs Score =

To calculate METS

Physical Activity in a typical week

- 1a During the last 7 days on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics or fast cycling? _____ days
- 1b How much time in total did you usually spend on one of those days doing vigorous physical activities? ____Hrs ____ Mins
- 2a During the last 7 days, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? (do not include walking) _____ days
- 2b How much time in total did you usually spend on one of those days doing moderate physical activity? ____Hrs ____Mins
- 3a During the last 7 days on how many days did you **Walk** for at least 10 minutes at a time? This includes walking at work and at home, walking to travel place to place and any other walking that you might solely do for recreation, sport, exercise or leisure _____ days
- 3b How much time in total did you usually spend walking on one of those days? ____Hrs ____Mins
- 3c At what pace do you **usually** walk?

Vigorous pace ☐ Moderate pace ☐ Slower pace ☐

$$\begin{aligned}\text{METS} = & (8 \times \text{VigorousDays} \times \text{VigorousMinutes}) \\ & + (4 \times \text{ModerateDays} \times \text{ModerateMinutes}) \\ & + (3.3 \times \text{WalkingDays} \times \text{WalkingMinutes})\end{aligned}$$

APPENDIX C: letter of permission to use Trust data

Letter of permission to conduct evaluation ~ Appendix 1
Version 1 – June 2014

Warrington and Halton Hospitals

NHS Foundation Trust

Halton General Hospital
Hospital Way
Runcorn
Cheshire
WA7 2DA

Hospital Switchboard: (01928) 714567

Warrington Hospital
Lovely Lane
Warrington
Cheshire
WAS 1QG

Hospital Switchboard: (01925) 635911

Date: 09/06/2014

To whom It may concern

Iona Taylor has permission to use data from Halton's Weight Management Service to conduct a service evaluation for her MSc dissertation in Weight Management.

Kind regards

APPENDIX D: ethical approval



University of
Chester

Faculty of Life Sciences
Research Ethics Committee

frec@chester.ac.uk

19th June 2014

Dear Iona,

Study title: Retrospective study comparing outcomes between type 2 diabetic and non-type 2 diabetic patients in an NHS Specialist Weight Management dietetic service.

FREC reference: 949/14/IT/CSN

Version number: 1

Thank you for sending your application to the Faculty of Life Sciences Research Ethics Committee for review.

I am pleased to confirm ethical approval for the above research, provided that you comply with the conditions set out in the attached document, and adhere to the processes described in your application form and supporting documentation. However, the Committee would like to request the following amendment:-

- On the Food Frequency Questionnaire, remove the first section 'Since you started the Fresh Start Programme ...'

JU36/8

Research Project

Please forward an electronic copy of the revised Questionnaire to frec@chester.ac.uk

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Application Form	1	May 2014
Appendix 1 – Written Permission, Warrington and Halton Hospitals NHS Foundation Trust	1	May 2014
Appendix 2 – Medical Record Policy (pg. 12)	1	May 2014
Appendix 3 – List of References	1	May 2014
Appendix 4 – Food Frequency Questionnaire	1	May 2014
Appendix 5 – Metabolic Equivalent Questionnaire	1	May 2014
Appendix 6 – Record Card	1	May 2014
Appendix 7 – Weight Record Form	1	May 2014
Appendix 8 – C.V. for Lead Researcher	1	May 2014
Appendix 9 – Records Management: Code of Practice (pg. 65-66)	1	May 2014

Please note that this approval is given in accordance with the requirements of English law only. For research taking place wholly or partly within other jurisdictions (including Wales, Scotland and Northern Ireland), you should seek further advice from the Committee Chair / Secretary or the Research and Knowledge Transfer Office and may need additional approval from the appropriate agencies in the country (or countries) in which the research will take place.

With the Committee's best wishes for the success of this project.

r. Stephen Fallows

Chair, Faculty Research Ethics Committee

Enclosures: Standard conditions of approval.

Cc. Supervisor/FREC Representative

APPENDIX E: care record card

SURNAME:		WARRINGTON AND HALTON HOSPITALS NHS FOUNDATION TRUST	
FORENAME:		DEPARTMENT OF NUTRITION & DIETETICS	
ADDRESS: POSTCODE.....		SECTION A TO BE COMPLETED BY REFERRER	
TEL NO: DATE OF BIRTH: HOSPITAL NO:		WARD/CLINIC	
DIAGNOSIS & MEDICAL HISTORY		RELEVANT BIOCHEMISTRY	
		WEIGHT:..... HEIGHT:	
		IDEAL WEIGHT RANGE:.....	
		NUTRITION SCORE:.....	
		BMI:.....	
		REFERRER:.....	
DIETARY ADVICE REQUESTED		CONSULTANT:.....	
RELEVANT MEDICATION		GP:..... DATE:	
		
		
SECTION B FOR DIETETIC STAFF		DATE FIRST SEEN:.....	
WEIGHT/DIETING HISTORY	SOCIAL HISTORY/MOTIVATION	LIFESTYLE FACTORS	
PROBLEMS IDENTIFIED	AGREED OBJECTIVES FOR BEHAVIOUR/DIET CHANGE		DATE ACHIEVED
	1
	2
	3
	4
	CLINICAL OUTCOME MEASURES		
	1
	2
3	
COMMUNICATION / DOCUMENTATION		DIET SHEET GIVEN	
REFERRAL ACKNOWLEDGEMENT LETTER	<input type="checkbox"/>		
MEDICAL NOTES ENTRY	<input type="checkbox"/>	FOLLOW UP	